

Application No.: 09/886,942

Page 2

**AMENDMENTS TO THE SPECIFICATION:**

Pursuant to the proposed revisions to 37 C.F.R. § 1.121, please amend the specification as follows:

Please replace the paragraph beginning at page 26, line 12, with the following rewritten paragraph:

Generally speaking, a "co-stimulatory molecule" refers to a molecule that acts in association or conjunction with, or is involved with, a second molecule or with respect to an immune response in a co-stimulatory pathway. In one aspect, a co-stimulatory molecule may be an immunomodulatory molecule that acts in association or conjunction with, or is involved with, another molecule to stimulate or enhance. ~~In stimulator-enhancer~~ In another aspect, a co-stimulatory molecule is an immunomodulatory molecule that acts in association ~~in association~~ or conjunction with, or is involved with, another molecule to inhibit ~~to inhibit~~ or suppress an immune response. A ~~an immune response~~ co-stimulatory molecule need not act simultaneously with, or by the same mechanism, as the second molecule. Exemplary co-stimulatory molecules include, e.g., B7-1 (CD80) and B7-2 (CD86) polypeptide ligands, which are expressed on antigen-presenting cells and act with an antigen in the stimulation of a T cell receptor to effectuate an immune response. Additional co-stimulatory molecules include CD54 or CD50 (ICAM), CD11a/18 (LFA-1) CD40, and ICOS (B7-H) which are also expressed on antigen-presenting cells. Other co-stimulatory polypeptides include, respectively, polypeptides that bind CD28 and/or CTLA-4 receptors on T cells (see, e.g., copending, commonly assigned US Patent Application Serial No. 09/888,324, [\_\_\_\_\_] entitled "Novel Co-Stimulatory Molecules," filed June 21, 2001 as LJAQ Attorney Docket No. 02-106720US (169.310US).

Please replace the paragraph beginning at page 28, line 31, with the following rewritten paragraph:

The promoter/enhancer elements can also be used to express co-stimulatory molecules, including, e.g., B7-1 and B7-2 ligands, CD54 or CD50 (ICAM), CD11a/18 (LFA-1) CD40, and ICOS (B7-H). Other co-stimulatory polypeptides include, respectively, polypeptides that bind CD28 and/or CTLA-4 receptors on T cells (see, e.g., copending, commonly assigned US Patent Application Serial No. 09/888,324, [\_\_\_\_\_] entitled "Novel Co-Stimulatory Molecules," filed June 21, 2001 as LJAQ Attorney Docket No. 02-106720US (169.310US). The

Application No.: 09/886,942

Page 3

promoter/enhancer elements can also be use to express adjuvants, *etc.* In all of these embodiments, the improved (optimized) CMV promoter/enhancer elements can be used both in animal and human models and in a variety of applications, including therapeutic and prophylactic treatment methods described herein.

Please replace the paragraph beginning at page 45, line 10, with the following rewritten paragraph:

Vectors of the present invention comprising at least one recombinant promoter of the present invention can be designed to include one or more nucleic acid sequences that express one or more modulators, immunomodulators, or immunostimulatory molecules. Optimized immunomodulators, immunostimulatory molecules and methods for obtaining optimized ~~immunomodulators~~ ~~immunomodulators~~ and immunostimulatory molecules are described in commonly assigned PCT Application No. US99/03020 (WO 99/41368), entitled "Optimization of Immunomodulatory Properties of Genetic Vaccines," and copending, commonly assigned US Patent Application Serial No. 09/888,324, [\_\_\_\_\_,] entitled "Novel Co-Stimulatory Molecules," filed on June 21, 2001 as LJAQ Attorney Docket No. 02-106720US (169.310US), each of which is incorporated herein by reference in its entirety for all purposes. These optimized immunomodulatory or immunostimulatory sequences are particularly suitable for use as components of the multicomponent genetic vaccines of the invention. Multiple modulators can be expressed from a monocistronic or multicistronic form of the vector. One or more vectors comprising optimized promoters of the invention can be used in conjunction with or as multicomponent genetic vaccines, which are capable of tailoring an immune response as is most appropriate to achieve a desired effect (*see, e.g.*, commonly assigned PCT Application No. PCT/US99/03022 (WO 99/41369), entitled "Genetic Vaccine Vector Engineering," which is incorporated herein by reference in its entirety for all purposes).